



**U.S. Immigration
and Customs
Enforcement**

ICE Health Services Corps (IHSC)
Enforcement and Removal Operations
Immigration and Customs Enforcement

Continuous Quality Improvement Activities Guide

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Foreword

This Continuous Quality Improvement Activities Guide supplements the following IHSC Directive:

11-02 (ERO # 11834.1), *Continuous Quality Improvement/ Program*

This Guide also references the following guides and policies:

IHSC Root Cause Analysis Guide

11-06 Timeframe To Submit Medical Incident Reports

This Guide explains concepts, assigns responsibilities and details procedures for the Continuous Quality Improvement Activities which includes Quality Improvement/Quality Assurance and Risk Management Programs.

The intended audience is all IHSC personnel, including but not limited to, Public Health Service (PHS) officers and civil service employees supporting health care operations in ICE-owned or contracted detention facilities and to IHSC Headquarters (HQ) staff. This directive applies to contract personnel when supporting IHSC in detention facilities and at HQ. Federal contractors are responsible for the management and discipline of its employees supporting IHSC.

I. Overview of the Quality Improvement/Quality Assurance and Risk Management Programs

A. Purpose of Programs

The Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) Quality Improvement /Quality Assurance Program and the Risk Management Program are located within the Medical Quality Management Unit of IHSC. These two programs provide a framework for a collaborative, organization-wide, systematic approach to improving IHSC performance – Continuous Quality Improvement (CQI). This approach ensures Quality Improvement/Quality Assurance (QI/QA) and Risk Management (RM) staff members monitor, assess and improve the quality of patient care delivered at IHSC-staffed facilities.

B. Quality Improvement/Quality Assurance Program

A CQI/RM programs monitor and improve health care delivered in the ICE facilities staffed by IHSC personnel.

The QI/QA Program promotes a culture that efficiently and effectively advances performance improvement activities throughout IHSC. It aligns performance improvement efforts with IHSC's mission, vision, and values. Maintaining an evidence-based QI/QA program allows IHSC to systematically monitor important processes and outcomes at the aggregate level while supporting a rigorous RM program that captures events that require root cause analysis (RCA), peer-review or other corrective action.

C. Risk Management Program

The RM Program works in collaboration with the CQI/QA program to determine risk(s) to IHSC and utilizes methods designed to identify causes leading to adverse patient events. The program's goal is to help reduce injuries, financial loss, and property loss within the organization. Inextricably interconnected with patient safety, the four key functions related to RM include:

- Identifying general clinical and administrative areas that represent actual or potential sources of patient injury;

- Identifying and evaluating individual cases of undesirable or adverse occurrences/outcomes;

- Evaluating data to resolve problems; and

- Making recommendations for peer reviews when needed.

D. Staff Responsibilities

Assistant Director (AD), ICE Health Service Corps (IHSC)

The AD has the ultimate responsibility for establishing policies and standardizing procedures to improve organizational performance and facilitate the safe delivery of quality health care to all categories of detainees. He or she:

Exercises broad oversight of the IHSC QI/QA and RM programs and supports activities necessary to provide high quality, safe, cost-effective patient care.

Ensures the participation of all disciplines in organizational QI/QA and RM activities.

Requires assessment activities that adequately scrutinize the safety, appropriateness, efficiency and efficacy of the health care services provided.

Ensures the patient safety functions are integrated within the QI/QA and RM activities throughout the organization.

Ensures adherence to requirements for American Correctional Association (ACA), National Commission on Correctional Health Care (NCCHC), and Performance-Based National Detention Standards (PBNDs).

Senior Leadership:

Reviews QI/QA and RM reports with the recommendations from the IHSC National Quality Improvement Committee.

Prioritizes and provides guidance based on information from data analysis to identify system and/or process changes that will improve performance or patient safety.

Chief, Medical Quality Management Unit:

Provides ultimate oversight and responsibility for ensuring that IHSC-wide QI/QA and RM are dynamic programs based on ongoing identification of opportunities for change.

Collaborates with Senior Leadership to develop policies and procedures for all regulatory and accrediting requirements associated with performance improvement and patient safety.

Forwards to Senior Leadership the recommendations that require action from the IHSC National Quality Improvement Committee.

Ensures organizational support for implementation of QI/QA, RM and patient safety activities.

Acts as consultant for performing and reviewing RCA to ensure the process is appropriately completed.

Acts as liaison to and collaborates with the Medical Case Management Unit, providing guidance on standards and ensuring non-compliance issues are addressed appropriately in IHSC and non-IHSC facilities.

CQI - Risk Management Program Manager (located at IHSC HQ)

This is a collaborative position with the QI/QA Program Manager.

Guides IHSC staff regarding the RM program, and collaborates with the National QI/QA Program Manager to identify, assess and proactively reduce litigation risk and adverse patient events.

Provides oversight of the activities of the CQI-Risk Management Coordinator and the Risk Management team

Collaborates with Compliance Investigators in reviewing and limiting potential risk management occurrences to IHSC.

Participates in the development, review and revising of the Risk Management Guide at least annually.

Collaborates with the IHSC Medical Education and Development Unit to develop training to meet the needs of staff based on data and identifies needs.

Submits quarterly reports of activities to the MQM Unit Chief

Conduct compliance site visits, as assigned

Performs other duties as assigned.

CQI - Risk Management Coordinator (located at IHSC HQ)

Supports the activities of the CQI-Risk Management Program

Provides guidance to IHSC staff regarding the RM program, and collaborates with the National QI/QA Coordinator to identify, assess and proactively reduce risk to the organization.

Coordinates and manages the RCA process.

Provides guidance and consultation to staff regarding risk management activities, correctly completing the RCA and incident reports.

Monitors, tracks and reviews incident reports to determine potential risk to IHSC

Conduct compliance site visits, as assigned

Performs other duties as assigned

Compliance Administrator – Continuous Quality Improvement/Quality Assurance Program (located at IHSC HQ)

The Compliance Administrator-CQI Program manages the activities and oversight of the IHSC CQI/PI Program, utilizing a variety of activities, tools and methods to improve quality, assess, and proactively reduce risk, and ensure safe practices are being utilized. This is a supervisory position.

Guides, consults and provides technical assistance on administrative and/or clinical issues to educate and clarify standards of care, practice and policy.

Chairs the IHSC National Quality Improvement Committee

Assist HSAs with local CQI Coordinator assignment and keep track of all current coordinators

Coordinate monthly/quarterly national CQI coordinator meetings; ie. scheduling, agenda, meeting minutes, etc.

Directs the collection, analyses, and dissemination of QI/QA data within IHSC, ensuring that basic statistical analyses and comparative processes are included

Monitors trends in processes and outcome of care, and reports the results to Senior Leadership, local facility leadership and external sources, as appropriate

Assists IHSC-staffed facilities identify opportunities for QI/QA, recommends solutions for facility issues and concerns, and implements plans and follow-up activities related to organizational QI/QA

Evaluate CQI program and activities at field sites and provide evaluation reports with recommendations for change, modifications or health and safety needs of the field to the HSAs and IHSC management, respectively

Assists with the development and implementation of QI/QA education and training for all IHSC staff

Collaborates with various key staff to ensure the integration of the quality functions are performed by IHSC staff

Participates in the development of policies for IHSC, reviews and/or revises the IHSC National QI/QA Plan at least annually

Oversees the preparation of intra- and inter-organizational QI/QA reports that demonstrate evidence of collaborative, multi-disciplinary input

Keeps senior leadership informed of public policies, regulations, guidance, and legislative and health care trends that affect various QI/QA, patient safety and other related health care initiatives

Collaborates with the IHSC Medical Education and Development Unit to develop training to meet the needs of staff based on data and identified needs

Submits quarterly reports of activities to the MQM Unit Chief

All activities listed under CQI Coordinator

Conduct compliance site visits, as assigned

Performs other duties as assigned.

National Continuous Quality Improvement (CQI) Coordinator (located at IHSC HQ)

The National CQI Coordinator is responsible for supporting the activities of the National CQI Program. This is a non-supervisory position.

Assists IHSC-staffed facilities to identify opportunities for QI/QA, recommends solutions for facility issues and concerns, and implements plans and follow-up activities related to organizational QI/QA.

Provides technical assistance, advice and consultation to field staff in interpreting and applying CQI related standards, regulations and policies.

Monitors trends in processes and outcome of care, and reports the results to Senior Leadership, local facility leadership and external sources, as appropriate

Conduct random chart audits to identify and assess any process or system failures

Tracking and reporting of quarterly audit results from all facilities and determine accuracy and appropriateness of data based on policy and processes

Facilitates the development and implementation of CQI education and training for all IHSC staff.

Directs the collection, analyses, and dissemination of QI/QA data within IHSC, ensuring that basic statistical analyses and comparative processes are included

Collaborates with various key staff to ensure the integration of the quality functions are performed by IHSC staff.

Assists with completing assigned reports

Performs other duties as assigned.

National Quality Improvement Committee

Provides operational leadership of continuous QI/QA activities at all levels of IHSC.

- Note: Operational leadership is an approach to help identify factors that maximize operational performance and aids in assessing and managing risks.

Identifies, prioritizes, implements and evaluates opportunities to improve organizational processes and systems.

Reviews and approves QI/QA measures and indicators annually.

Develops recommendations for QI/QA activities according to potential impact upon patient outcomes and safety.

Facilitates a multidisciplinary collaborative approach to improving the quality of patient care and safety, and appropriate utilization of resources.

Facilitates the development and implementation of QI/QA education and training for all IHSC staff.

Health Services Administrators (HSAs) and Clinical Directors (CDs)

Oversee and integrate QI/QA, RM and patient safety activities (in conjunction with the Environmental Health and Safety Officer, as appropriate) in their local facilities. Appoints a local QI/QA Coordinator to perform these activities.

Review plans, reports, and correspondence of the facility QI/QA activities with a focus on interdisciplinary collaboration.

Provide support and assistance to IHSC and ERO staff involved in sentinel events.

Local Quality Improvement Committee

Each medical facility's Governing Body establishes and maintains a local QI Committee for the purpose of improving performance and promoting patient safety.

The QI Committee is a multidisciplinary team (IHSC staff members) determined by the Governing Body. The responsible physician is involved in the CQI committee.

The QI Committee meets at least quarterly to discuss identified areas of improvement.

The QI Committee identifies local problems from the QI Quarterly Report, Incident Reports, local surveys/audits, and other means and assigns an individual or team to conduct process or outcome studies on these locally identified problems.

The QI Committee assigns a team to complete a Healthcare Failure Modes and Effects Analysis (HFMEA). All facilities, to include Staging Facilities, must complete a HFMEA annually.

The QI Committee completes an annual review of the effectiveness of the CQI program by reviewing CQI studies and minutes of CQI, administrative and/or staff meetings, or other pertinent written materials.

Local Quality Improvement Coordinator

Serves as the liaison between the local QI Committee and the National QI/QA Coordinator.

Chairs the Local QI Committee.

Represents his or her medical facility by participating in quarterly National QI meetings.

Coordinates the local quality improvement activities and ensures that data is reported to IHSC HQ as requested.

Ensures that all IHSC field staff are trained initially and annually regarding the QI/QA program.

Develops local metrics and implements action plans as needed in addition to those identified by the National QI Committee incorporating all applicable patient safety initiatives throughout the organization.

Submits quality improvement reports to the National QI/QA Coordinator on a quarterly basis.

All IHSC personnel

Fully understand and take responsibility for their individual roles in quality improvement, risk management, and patient safety.

Actively participate in creating a safe environment by meeting organizational and professional standards, following identified best/safe practices, and proactively mitigating unsafe conditions or situations.

Complete organization/unit-based orientation and participate in ongoing patient safety education.

Voluntarily report all close calls/near misses, adverse events, and/or sentinel events.

Initiate immediate steps to ensure patient and staff safety by securing any supplies/equipment that may have precipitated a Patient Safety event.

Educate patients on their roles and responsibilities to facilitate the safe delivery of care.

Stay current on recommended best/safe practices and safety alerts.

Definitions

See the IHSC Glossary located at: [GLOSSARY FOR IHSC OFFICIAL GUIDANCE](#).

II. Program Methodology

A. Measurement

The QI/QA and RM Programs are based upon data collection and analysis to assess organizational performance in the quality of clinical patient care, the efficiency and effectiveness of the delivery systems and the level of service provided during the delivery of those services. Data collection occurs at many levels throughout IHSC on a variety of important functions, but the following IHSC-wide functions are most important to the delivery of patient care services and achieving good patient outcomes.

Patient Focused Functions

Patient's Rights:

- Access to Care;
- Quality of Care;
- Grievances;
- Limited English Proficiency Services; and
- Reasonable Accommodations.

Provision of Patient Care, Treatment and Services:

- Chronic Care;
- Pregnancy;
- Health Assessment;
- Continuity of Care;
- Treatment of Disability;
- Laboratory and Diagnostics; and
- Sick Call.

Medication Management:

- Medication Errors;
- Continuity of Medication;
- Medication Refusal; and
- Pharmacy Monitoring (Asthma drugs, Coumadin, Diabetes drugs, Psychotropics)

Organizational Functions

Improving Organizational Performance:

- CQI Program Assessment;
- Process Studies;
- Outcome Studies;
- Healthcare Failure Mode and Effect Analysis (HFMEA); and
- Staff Satisfaction Surveys;

Management of Environment of Care:

- Incident Reports; and
- Root Cause Analysis (RCA) and Corrective Action Plans (CAP).

1. Quality Indicators

Indicators are developed to measure and monitor the performance and stability of processes used in delivering patient care services and the associated outcomes. Indicators measure both processes and outcomes in an objective method, and may include clinical standards or other applicable professional guidelines. Special attention is given to the development of indicators for those processes and/or outcomes which are high risk, high volume, tend to be problem prone, and/or offer opportunities for improvement. The goal of indicator development, data collection and analysis is to quantify the level of performance improvement and to determine if performance improvement initiatives have met their goals.

Quality indicators are developed at various levels throughout the organization and contain measures of the quality of patient care, the efficiency and effectiveness of the processes used to provide that care.

2. Data Source

The QI/QA program manager collects data used in the assessment of organizational performance and the quality of care from several sources, including but not limited to:

- Patient encounters;
- Patient incidents;
- Risk management program;
- Surveys; and
- Detainee health records.

B. Analysis

The analysis process identifies and prioritizes opportunities for improvement. The QI/QA program manager identifies patterns, trends and opportunities for improvement at both the organizational and at the facility level. Data collected through the QI/QA Program is analyzed, prioritized, presented and acted upon by multiple-disciplines.

IHSC uses statistically valid, aggregate data to determine causes of process and outcome variation. The assessment of process and outcomes data may include comparing performance to:

- clinical practice guidelines or practice parameters
- organizational policies
- regulatory standards

C. Improvement

When QI/QA team members identify opportunities for improvement through data collection and analysis, and subsequently prioritize the opportunities for action, they use the “Plan, Do, Check, Act” (PDCA) methodology to make the improvement.

- **Plan:** Planning health care delivery, and a system to evaluate its effectiveness, requires not only the involvement of facility health care staff, but leadership as well.
- **Do:** Do or deliver the planned services. While delivering services, staff also measures those functions or processes identified as high risk, high volume, or problem prone.
- **Check:** When evaluating the results of what is done, or measuring quality, staff should check against previously measured results at their facility, or compare results against other comparable services measured at similar facilities.

- **Act:** Based on results, staff recommends improvement strategies to their leadership: additional training, education, etc. The local leadership assesses the QI program's effectiveness annually.

D. Reporting

QI data collection and reporting improves organizational systems and provides the safest patient care possible. Standardized data reporting processes across the organization leverage best practices.

In an effort to examine trends in reported events across the organization, each IHSC facility, at a minimum, systematically collects identified core measures. Core measures are standardized performance measures within a multi-system organization that can be applied across each facility. Core measures accurately capture patient safety related events and allow the organization an opportunity to track and trend aggregate data for effective analysis.

QI/QA staff develops customized ad hoc queries and reports as directed by IHSC headquarters.

Detailed data analysis using queries and reports provides useful information to any level of management. This information highlights the various contributing factors associated with patient safety events and facilitates decision-making regarding the specific process improvement required to prevent recurrence.

Each facility must report on core measures and any other measures specified by the QI/QA Coordinator quarterly in the time frame indicated in Appendix E.

The two types of reviews include:

- Record reviews:
 - Health staff must review all encounters that occurred within the quarter in which reporting is performed.
 - Health staff conducts random sampling of records to ensure that each provider is adequately reviewed. This identifies any potential training areas before the occurrence of an adverse outcome.
- Cumulative reviews of incidents:
 - Health staff uses cumulative totals for incidents.
 - The clinical medical authority determines when an improvement strategy is needed and develops an improvement plan.

The quarterly QI/QA report should consist of:

- Type of review (record or cumulative)
- Source of information (medical record, incident reports, inspection reports, etc.)

- Analysis and Improvement Plan (if falls below compliance threshold; determined by the QI Program Manager)

E. Annual Program Assessment

Each facility performs an annual assessment of its current quality improvement program, according to the quality improvement annual schedule, using the guidelines provided by the Medical Quality Management Unit.

The QI coordinator, in collaboration with the HSA and the clinical medical authority, identifies and prioritizes high-risk processes and includes the prioritized processes in the facility quality improvement annual plan. The QI coordinator then completes formal analysis and improvement strategies for these process improvements.

F. Incident Reports

All IHSC staff members can identify that a suspected clinical incident occurred. Patients, family, advocates, ICE staff, detention staff, etc., may also identify suspected clinical incidents. All IHSC staff will report clinical incidents using the IHSC Sharepoint Site, *IHSC Incident Reports*. The timeframes for which incident reports should be submitted is found in the IHSC Directive 11-06 *Time Frame for Submitting Incident Reports*, located within the following folder: Book 11-Quality Improvement. It is important for all staff to recognize when a suspected clinical incident occurred. If you are unsure whether the incident is, or has the potential to be, a near-miss, adverse event, or sentinel event, err on the side of caution and proceed as if it were. Staff is encouraged to over report incidents because an incident is not categorized as a clinical incident until the conclusion of an investigation into the matter.

G. Root Cause Analysis (RCA) – See also IHSC RCA Guide located within folder: [All Guides](#)

The RCA identifies basic and/or contributing causal factor(s) associated with patient safety and sentinel events.

This interdisciplinary review includes those who are closest to the process.

The primary focus is on systems and processes, however, individual performance can be reviewed as necessary.

The analysis determines “what” and “why” until all aspects of the process are reviewed, and all contributing factors have been determined.

RCA identifies changes that could be made in systems and processes to improve performance and reduce the risk of adverse events or recurrence of close calls.

A powerful tool, the RCA process looks retrospectively at the events that occurred to determine the cause of a sentinel/patient event.

H. Healthcare Failure Mode and Effect Analysis (HFMEA)

A systematic prospective risk reduction assessment methodology identifies and improves steps in a process before they occur, thereby reasonably ensuring a safe and clinically desirable outcome.

A bottom up approach to analyzing processes, system designs and performance

This proactive tool can be used to improve processes throughout the organization.

References

ICE Health Service Corps (IHSC), Root Cause Analysis Guide.

National Commission on Correctional Health Care (NCCHC). Guidelines for the Management of an Adequate Delivery System (2001).

Veterans Administration National Center for Patient Safety, The Basics of Healthcare Failure Mode Effects and Analysis (HFMEA), 2001.

Medical Command Regulation No. 40-41, The Patient Safety Program, 14 Jan 2002.

Military Health System (MHS) Patient Safety Program (PSP), Number 6025.17, 16 Aug 2001.

Army Regulation 40-66, Medical Records and Quality Assurance Administration, 3 May 99.

Army Regulation 40-68, Quality Management, 20 Feb 04.

Medical Quality Management Directive; DHS MD Number 248-01 (October 2, 2009).

Medical Quality Management Instruction; DHS Instruction Number 248-01-001 (September 10, 2012).

Appendix A

Definitions

Action plan- The end product of a Root Cause Analysis or Healthcare Failure Mode and Effects Analysis that identifies the risk reduction strategies the organization intends to implement to prevent the recurrence of similar adverse events in the future. (IHSC Operational Definition)

Actual event- A situation or circumstance that did occur either with or without harm to the patient. (IHSC Operational Definition)

Adverse event- An adverse event is an occurrence or condition associated with the provision of health care or services that caused harm to the patient. Adverse events may be due to acts of commission or omission. (from DHS Directive #248-01-001, Medical Quality Management)

Aggregate- To combine standardized data and information collected over time. (IHSC Operational Definition)

Assessment- The systematic collection and review of patient specific data. (IHSC Operational Definition)

Close Call- See “Near Miss”

Core measures- Standardized performance measures that can be applied across health care accreditation programs. (IHSC Operational Definition)

Criteria- Expected level of achievement, or specifications against which performance or quality may be compared. (IHSC Operational Definition)

Data- Material facts or clinical observations that have not been interpreted.

Evaluation- Analysis of collected, compiled, and organized data pertaining to important aspects of care. Data are compared with predetermined, clinically valid criteria; variations from criteria are determined to be accepted or unaccepted; and problems or opportunities to improve care are identified.

Governing Body- Refers to the individuals, group, or agency that has ultimate authority and responsibility for establishing policy, maintaining quality of care, and providing for organizational management and planning. (IHSC Operational Definition)

Healthcare Failure Mode and Effect Analysis (HFMEA) - The HFMEA is a systematic prospective risk reduction assessment methodology that identifies and improves steps in a process before they occur, thereby reasonably ensuring a safe and clinically desirable outcome. HFMEA is a bottom-up approach to analyzing processes, system designs and performance.

Measure- To collect quantifiable data about a dimension of performance of a function or process. (IHSC Operational Definition)

Measurement- The systematic process of data collection, repeated over time or at a single point in time. (IHSC Operational Definition)

Near Miss (also known as Close Call)- An event or situation that could have resulted in harm to a patient but did not, either by chance or through timely intervention. The event was

identified and resolved before reaching the patient. Such events have also been referred to as “close call” incidents.

Outcome Study- An outcome study examines whether expected outcomes of patient care were achieved by (1) identifying a patient clinical problem; (2) conducting a baseline study; (3) developing and implementing a clinical corrective action plan; and (4) restudying the problem to assess the effectiveness of the corrective action plan.

Outcome- The result of the performance (or non-performance) of a function or process. (IHSC Operational Definition)

Patient safety event- An incident or error that occurred (actual event), or almost occurred (close call/near miss), that caused, or had the potential for causing, harm to a patient. (IHSC Operational Definition)

Performance improvement (PI)- The continuous study and adaptation of functions and processes to increase the probability of achieving desired outcomes and better meeting the needs of individuals, populations and other users of services.

Process- A goal-directed, interrelated series of actions, events, mechanisms, or steps. A systematic series of actions directed to the achievement of a goal.

Process Study - A process study examines the effectiveness of the health care delivery process by (1) identifying a facility problem; (2) conducting a baseline study; (3) developing and implementing a clinical corrective action plan; and (4) restudying the problem to assess the effectiveness of the corrective action plan.

Quality Assurance (QA) – Systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that nationally recognized standards of care are being met. ([DHS Directives System - Instruction # 248-01-001, Revision 1 - Medical Quality Management](#))

Quality Improvement (QI) - Quality improvement is a prospective and retrospective review aimed at improvement: measuring where you are, and figuring out ways to make things better. It specifically attempts to avoid attributing blame, and to create systems to prevent errors from happening.

Risk assessment- A method used to proactively evaluate the probability of a patient safety event in order to minimize the risk of the event actually occurring. (IHSC Operational Definition)

Risk management- Clinical and administrative activities that organizations undertake to identify, evaluate, and reduce the risk of injury to patients, staff and visitors, and the risk of financial loss to the organization. It involves identification of risk potential, prevention of risk exposure, and the management of real or potential adverse incidents and medical malpractice claims. (IHSC Operational Definition)

Root cause analysis (RCA) - A process for identifying the basic or contributing causal factors(s) associated with an adverse and/or sentinel events. The review is interdisciplinary and includes those who are closest to the process. It identifies changes that could be made in systems and processes to improve performance and reduce the risk of adverse events or recurrence of close calls. (IHSC Operational Definition)

Sentinel event (SE) - An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof that is not related to the natural course of the patient's

illnesses or underlying condition. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof", includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

Standard- A statement of expectation that defines the structures and processes that must be substantially in place in an organization to enhance the quality of care. (IHSC Operational Definition)

Appendix B

SENTINEL EVENTS/ROOT CAUSE ANALYSIS

A SENTINEL EVENT is defined as an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof that is not related to the natural course of the patient's illnesses or underlying condition. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof", includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

Serious injury specifically includes, but is not limited to, a permanent loss of limb or function.

I. Sentinel event criteria

- A. Unanticipated death (not expected or foreseen) of a detainee while at a Service Processing Center or at another facility to which a detainee was transferred for medical care including those related to any healthcare acquired infection.
- B. Attempted suicide, suicide, serious injury, loss of limb, or major permanent loss of function, including those related to any healthcare acquired infection.
- C. Serious medication error.
- D. Patient abuses (physical, sexual, or psychological) by medical clinic staff personnel or other patient/ perpetrator in the health care setting.
- E. Surgery on wrong patient or wrong body part.
- F. Unintended retention of foreign object in a patient after surgery or other procedure.

II. Incident Reports

- A. The individual staff member discovering an incident completes the IHSC Incident Reporting on Sharepoint, utilizing the guidelines provided in IHSC Directive 11-06, *Time Frame for Submitting a Medical Incident Report* and the Incident Report Tip Sheet. The tip sheet provides guidance on completing and submitting incident reports, and is housed at: S:\IHSC\Medical Quality Management\RCA Sentinel Events\Additional Risk Management Guidance and Resources for IHSC Staff\Guidance on Incident Reports
- B. After completing the incident report, the staff member saves and submits the document to their Health Services Administrator (HSA).
- C. The HSA reviews the incident report, and documents his or her findings. The HSA will forward the incident report to ensure it has been reviewed by the Clinical Director (CD) and local Quality Improvement Coordinator.

- D. The HSA saves and submits the incident report to the MQM incident report via Sharepoint Incident Report site
- E. MQM staff reviews every incoming incident report. As appropriate, they follow-up with the facility to obtain any additional information necessary to determine whether further action is warranted.
- F. If requested by the MQM Unit, the facility prepares a Sequence of Events regarding the incident, and emails to the MQM Unit.
- G. MQM reviews the Sequence of Events (the initial step in the RCA process) and determine whether further action, such as a full Root Cause Analysis, is warranted.

III. Root Cause Analysis (RCA) process

Refer to the Root Cause Analysis Guide located at [All Guides.](#)

Appendix C

Healthcare Failure Mode and Effect Analysis

The Healthcare Failure Mode and Effect Analysis (HFMEA) is a team-based, proactive, systematic approach to risk reduction. Unlike a Root Cause Analysis, which is reactive ("why did the process/system fail?"), HFMEA looks at ways a process **may** fail or breakdown ("how could the process/system fail?"), how the process can be improved so it is less likely to fail or breakdown, and more importantly, fixing the weaknesses before an event occurs. The HFMEA can be conducted on a process that is already in place, or can be conducted on a process that is being considered for implementation.

HFMEA is a 5-step process that uses an interdisciplinary team to proactively evaluate a health care process. The team uses process flow diagramming, a Hazard Scoring Matrix, and the HFMEA Decision Tree to identify and assess potential vulnerabilities.

Step 1: Define the HFMEA Topic

The topic to be reviewed should be a high-risk or high-vulnerability area (as determined by the quarterly PI report or other means), to merit the investment of time and resources by the HFMEA team.

Facilities can focus on a part of the process, especially if it is a major and complex process. Consider focusing on processes within your facility that pose the most risk to your patients' safety. Focusing on a specific part of the process keeps the team on track and allows timely completion of the project without being overwhelming. Choose a manageable and focused process or specific part of the process (sub-process) that allows the team to conduct an effective HFMEA that will find and fill all the critical failure modes within those process boundaries.

Step 2: Assemble the team

A multidisciplinary team should include subject matter expert(s) of the process and a team leader. A multidisciplinary team ensures that various viewpoints are considered. At least one member who is unfamiliar with the process should be included on the team to encourage a critical review of accepted standards and practices and identification of potential vulnerabilities that others might miss.

Step 3: Graphically Describe the Process

The team should clearly define each step of the **actual process** by consecutively numbering each process step (i.e. 1, 2, 3...). Next, identify all sub-processes under each step and consecutively letter these sub-process steps (i.e. 1A, 1B...3A, 3B...). Teams will find it extremely beneficial to identify all sub-process steps before proceeding with further team work. If the process is complex, identify the portion of the process or sub-process to focus on (This process does not have to utilize the flow chart format; it can be illustrated in an outline format). The best way to ensure that the true process is captured is to have a team member(s) observe the process and verify the process steps are correct.

Step 4: Conduct a Hazard Analysis

For each step in the process, list all possible/potential failure modes for each of the sub-processes and consecutively number these failure modes (i.e. 1A(1), 1A(2)...3E(1)...). When analyzing the process for failure modes, think about what the desired outcome of your process is and what could happen to prevent the desired outcome. Failure modes are operationally defined as the different ways that a particular process or sub-process step can fail to accomplish its intended purpose. For example, if the sub-process step is confirming known drug allergies, failure modes would include the following: (1) not recording drug allergies and (2) incompletely capturing drug allergies. The team is encouraged to use various sources and tools to identify potential failure modes.

Next, determine the severity and probability of the potential failure modes, and using the *Hazard Scoring Matrix*, conduct a hazard analysis that allows the team to estimate and prioritize the risk of the failure modes. The hazard analysis determines the severity, probability, and detectability of a failure mode. The severity score is a measure of the potential effect of the failure mode. The severity categories include catastrophic, major, moderate, and minor. The probability ratings include frequent, occasional, uncommon, and remote.

Hazard Scoring Matrix					
Probability	Severity of Effect				
		Catastrophic	Major	Moderate	Minor
	Frequent	(b)(7)(E)			
	Occasional				
	Uncommon				
	Remote				

FMEA PROBABILITY RATING

Frequent
(Score 4)

Likely to occur immediately or within a short period (may happen several times in one year)

Occasional
(Score 3)

Probably will occur (may happen several times in 1 to 2 years)

Uncommon
(Score 2)

Possible to occur (may happen sometime in 2 to 5 years)

Remote

Unlikely to occur (may happen sometime in 5 to 30 years)

Each failure mode may have a number of potential causes – situations that would cause the failure mode to occur. It is essential to focus on human factors, process and systems issues that may cause the failure modes. Analyze each cause and prioritize the causes that place the highest risks on your system.

The HFMEA Decision Tree is used to determine whether the failure mode warrants further action on the basis of criticality, absence of effective control measures, and lack of detectability:

Criticality (single point weakness) - measures whether the entire system will fail if this part of the process fails.

Effective control measure- eliminates or significantly reduces the likelihood of the failure occurring.

Detectability (obvious hazard) - is defined as the likelihood of detecting failure or the effect of failure before it occurs.

Step 5: Actions and Outcome Measures

Develop a description of action for each failure mode cause where the action is to proceed, identify outcome measures, and identify a single person responsible for completing or ensuring completion of each action. When developing actions, it is essential to consider the effects of that action on the entire process. A new way of doing something isn't always a better way. The goal is to eliminate or reduce that cause without creating new failure modes or potential causes in that or other parts of the process.

A critical step of HFMEA includes testing to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system or in other interdependent systems.

HEALTHCARE FAILURE MODES AND EFFECTS ANALYSIS (HFMEA) – page 1 of 4

One HFMEA will be conducted annually by each facility.

Step 1: Define the HFMEA Topic (include a clear definition of the process to be studied.)

This HFMEA focuses on:

Step 2: Assemble the Team (Team should be interdisciplinary including subject matter experts and an advisor.)

Date Started:

Date Completed:

Team Leader:

Team Members:

Are all affected areas represented? (Answer YES or NO)

Are different levels and types of knowledge represented on the team? (Answer YES or NO)

Who will take the minutes and maintain records?

Step 3: Describe the Process Being Analyzed (for example through a flow chart)

- A. Develop and verify the flow diagram (this is a process vs. chronological diagram)
- B. Consecutively number each process step identified in the process flow diagram.
- C. If the process is complex, identify the areas of the process to focus on (take manageable bites.)
- D. Identify all sub processes under each block of this flow diagram. Consecutively letter these sub-steps. (i.e. 1a, 1b...3e, etc.)
- E. Create a flow diagram composed of the sub processes. Consecutively letter these sub-steps.

(Hint: It is very important that all process and sub-process steps be identified before proceeding.)

Describe process here (either using flow chart or other means):

Step 4: Conduct a Hazard Analysis

A. Identify the ways in which the process could break down or fail to perform its desired function.

B. Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.

C. Prioritize the potential process breakdowns or failures.

D. Determine why the prioritized breakdowns or failures could occur, which may include conducting a hypothetical root cause analysis.

Step 5: Actions to Redesign Process and Outcome Measures

Description of action/ process changes taking as a result of analysis:
(if taking more than one action or changing more than one process, list each action or process change separately.)

Outcome Measures (Identify outcome measures that will be used to analyze and test the redesigned process.)

Person Responsible

Monitoring of Effectiveness (i.e. how often, what length of time, etc.)

Results:

Appendix D

PROCESS STUDY

Process studies examine the efficiency of various health care **procedures**.

The process the facility chooses should address a problem that is **specific to that facility**.

(Some examples: timeliness of intake screening process; completeness of the MARs; timeliness of sick call process; timeliness of follow-up post-discharge from suicide watch)

Problem areas may be identified during analysis of specific areas of the PI Report (it expands on your improvement strategy that you identified in the quarterly report), survey or inspection findings (NDS, ACA, NCCHC, JCAHO, etc.) or through other local means.

Facility Conducting Study: _____

Date submitted to IHSC HQ PI Coordinator: _____

Step 1: Decide what to study.

- High volume (e.g. intake process, sick call, pill line)
- High risk (e.g. chronic care visits, continuity of care post discharge)
- Problem prone (e.g. timeliness for appointments at the medical clinic due to security constraints.)

Specific Step 1 Example: Timeliness of appointments post hospital discharge.

Step 1:

Step 2: Decide how to measure efficiency or effectiveness.

- Review IHSC policies and procedures and any local procedures
- Review clinical practice guidelines
- Review nursing assessment protocols
- Other resources, as appropriate

Specific Step 2 Example: Patient seen within 3 days of return to the facility from hospitalization.

Step 2:

Step 3: Decide on the data source.

- Logs
- Forms
- Health records
- Statistical reports

Specific Step 3 Example: The log for off-site care will be utilized (name, number, date of hospitalization, date of discharge, date seen in facility's medical clinic.)

Step 3:

Step 4: Decide on the timeframe to review

- Prospective (used if existing data cannot answer the questions being asked.)
- Retrospective (used if existing data contain the elements under review in this study.
- Last year, last quarter, next three months, etc.

Specific Step 4 Example: Will review last quarter's off-site care log (time frame for quarter is October 1- December 31, 2007.)

Step 4:

Step 5: Decide on sample size.

This is a function of both the:

- data source selected
- time frame selected

Specific Step 5 Example: All discharges from the last quarter (October 1- December 31, 2007.)

Step 5:

Step 6: Decide on the sampling method.

- Random sampling
- Sampling a cohort
- Stratified sampling

Specific Step 6 Example: Entire cohort

Step 6:

Step 7: Decide on the thresholds for compliance.

Thresholds define the level of tolerance we have for error.

- thresholds should not be set artificially high or low
- 100% compliance should be used only for the most life-threatening or serious conditions.

Specific Step 7 Example: 95% compliance

Step 7:

Step 8: Decide who is going to conduct the study.

- Medical records staff or other administrative support staff can usually gather data for process elements (e.g. timeliness, completeness)
- Clinical staff are needed only when the appropriateness of clinical decision-making is at issue.

Specific Step 8 Example: Medical Record Technicians

Step 8:

Step 9: Conduct the study, analyze the results, and determine the appropriate corrective action.

Specific Step 9 Example: Study reveals that patients were seen within 3 days of discharge from the hospital only 75% of the time. Results show that hospital does not notify the medical clinic that detainee is being discharged, but rather ICE staff is notified. Will train ICE staff to notify medical (telephone notification to security officer on duty in the medical clinic); this officer will write the information in a discharge log that will be kept at the officer's desk at medical and that is reviewed by a nurse, mid-level or physician on the day shift.

Step 9:

Step 10: Implement the corrective action plan.

Specific Step 10 Example: Medical security officers were trained on the newly developed discharge log.
Medical clinic providers also trained on responsibilities for day shift staff to check the discharge log and schedule follow-up appointments.

Step 10:

Step 11: Repeat the study after some time has elapsed to determine whether the corrective action plan resulted in improvements.

Specific Step 11 Example: Repeat the study the next quarter.

Step 11:

Step 12: If no improvement, do a more focused review of the steps in the process.

Specific Step 12 Example: If no improvement next quarter, conduct a more thorough, team-centered HFMEA to determine where the process is breaking down.

Step 12:

Appendix E OUTCOME STUDY

Outcome studies examine **whether expected outcomes of patient care were achieved.**

The outcome study that your facility chooses should address a problem that is **specific to your facility.**

(Some examples: management of chronic care patients, management of mental illnesses, management of patients in the SSU/ infirmary.)

Problem areas may be identified during your analysis of specific areas of the PI Report (it expands on your improvement strategy that you identified in the quarterly report), survey or inspection findings (NDS, ACA, NCCHC, Joint Commission, etc.) or through other local means.

Facility Conducting Study: _____

Date submitted to IHSC HQ PI Coordinator: _____

Step 1: Decide what to study.

- High volume (e.g. intake screening completeness, sick call care)
- High risk (e.g. management of diabetes, management of suicidal patients)
- Problem prone (e.g. medication-related errors, communication between providers)

Specific Step 1 Example: Management of patients with bipolar disorder. Patients will have treatment plans that adhere to the American Psychiatric Association's Practice Guidelines for treatment of patients with bipolar disorder.

Step 1:

Step 2: Decide how to measure efficiency or effectiveness.

- Review medical records for specific criteria
- Review IHSC policies and procedures and any local procedures
- Review clinical practice guidelines
- Review nursing assessment protocols
- Review other resources, as appropriate

Specific Step 2 Example: Review of all bipolar-related treatment plans in the patient's medical record with focus on appropriateness, thoroughness, and effectiveness.

Step 2:

Step 3: Decide on the data source.

- Logs
- Forms
- Health records
- Statistical reports

Specific Step 3 Example: Patient's medical record

Step 3:

Step 4: Decide on the timeframe to review

- Prospective (used if existing data cannot answer the questions being asked.)
- Retrospective (used if existing data contain the elements under review in this study.
- Last year, last quarter, next three months, etc.

Specific Step 4 Example: Two quarters (April 1, 2007- September 30, 2007)

Step 4:

Step 5: Decide on sample size.

This is a function of both the:

- data source selected
- time frame selected

Specific Step 5 Example: 100% of records of patients diagnosed with bipolar disorder.

Step 5:

Step 6: Decide on the sampling method.

- Random sampling
- Sampling a cohort
- Stratified sampling

Specific Step 6 Example: Entire cohort

Step 6:

Step 7: Decide on the thresholds for compliance.

Thresholds define the level of tolerance we have for error.

- they should not be set artificially high or low
- 100 percent compliance should be used only for the most life-threatening or serious conditions.

Specific Step 7 Example: 90% compliance

Step 7:

Step 8: Decide who is going to conduct the study.

- Medical records staff or other administrative support staff can usually gather data for process elements (e.g. timeliness, completeness)
- Clinical staff are needed only when the appropriateness of clinical decision-making is at issue.

Specific Step 8 Example: Psychiatrist

Step 8:

Step 9: Conduct the study, analyze the results, and determine the appropriate corrective action.

Specific Step 9 Example: Study reveals that patients were seen within the time frame specified on the treatment plan only 75% of the time. Results show 95% compliance with adhering to the APA Guidelines for the treatment of bipolar disorder.

Mental health providers at the facility will be instructed to schedule patients for follow-up appointments for a date within the guidelines. This scheduling will take place immediately after each appointment.

Step 9:

Step 10: Implement the corrective action plan.

Specific Step 10 Example: Medical security officers were trained on the newly developed discharge log. Mental health providers at the facility were instructed to schedule patients for follow-up appointments for a date within the guidelines. This scheduling will take place immediately after each appointment. Training was provided on “how to schedule an appointment in the EMR.”

Step 10:

Step 11: Repeat the study after some time has elapsed to determine whether the corrective action plan resulted in improvements.

Specific Step 11 Example: Repeat the study the next quarter.

Step 11:

Step 12: If no improvement, do a more focused review of the steps in the process.

Specific Step 12 Example: If no improvement next quarter, the psychiatrist will conduct a 2 hour targeted training based on the problem areas identified during the chart reviews.

Step 12:

Appendix F
Quarterly Report Due Dates

<u>Quarters</u>	<u>Quarter Range</u>	<u>Reports Due</u>
Quarter 1	Oct 1- Dec 31	Jan 14
Quarter 2	Jan 1- Mar 31	April 14
Quarter 3	April 1- Jun 30	July 14
Quarter 4	July 1- Sep 30	Oct 14